

AMENDMENTS TO THE CLAIMS:

The following is a complete listing of the pending claims.

1. (Currently amended) A method of making a ~~collection~~ device (100) for collecting mammalian cells (20), comprising the steps of:
 - (a) providing a tube (12) for collecting a final composition (30) having a volume of 100 parts, said tube (12) having an open end (14) and a closed end (16);
 - (b) preloading compounds (22) including:
 - an anticoagulant agent (24), and
 - a fixative agent (26) into said tube (12), said fixative agent (26) selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoyl-5,5 dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof[[:]],~~wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells, and thereby allowing said cells to be directly analyzed by a flow cytometer without further treatment;~~
wherein said compounds (22) are in a volume of no greater than 2 parts;
 - (c) placing a closure (18) at said open end (14) of said tube (12); and
 - (d) ~~drawing an amount of vacuum inside said tube to a predetermined level, wherein said amount of vacuum to be drawn is such that pressure differential between atmospheric pressure outside said tube and pressure within said tube is at least sufficient to allow a predetermined volume of said cells to be collected~~
creating and maintaining a pressure differential between atmospheric pressure outside said tube (12) and a pressure less than atmospheric pressure within said tube (12).

2. (Currently amended) The method of Claim 1, wherein said anticoagulant agent (24) is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.
3. (Currently amended) The method of Claim 1, wherein the concentration of said fixative agent (26) preloaded in said tube (12) is less than about 1 g/ml.
4. (Currently amended) The method of Claim 1, wherein the concentration of said anticoagulant agent (24) preloaded in said tube (12) is less than about 0.3 g/ml.
5. (Currently amended) The method of Claim 1, wherein said preloading step further includes preloading a ~~polyaeylie~~ polyacrylic acid (28) into said tube (12).
6. (Cancelled)
7. (Previously presented) The method of Claim 1, wherein said cells are selected from the group consisting of whole blood, epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.
8. (Currently amended) The method of Claim 1, further comprising the step of sterilizing said compounds (22) prior to preloading step ~~before said compounds are preloaded into said tube.~~
9. (Cancelled)
10. (Currently amended) The method of Claim 1, further comprising the step of providing at least one component (32) selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis,

a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

11-13. (Cancelled)

14. (Currently amended) A ~~collection~~ device (100) for collecting mammalian cells (20) comprising:

(a) a collection container (10) for collecting a final composition (30) having a volume of 100 parts, said container (10) having an open end (14) and a closed end (16);[[,]]

(b) a closure (18) at said open end (14) of said container (10), wherein said container has an internal pressure less than atmospheric pressure outside said container; and

~~(b)~~(c) compounds (22) positioned within said container (10), wherein said compounds include an anticoagulant agent (24) and a fixative agent (26) selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoylol-5,5 dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof, ~~inside said tube, wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells, and thereby allowing said cells to be directly analyzed by a flow cytometer without further treatment.~~

wherein said compounds (22) are in a volume of no greater than 2 parts.

15. (Currently amended) The device of Claim 14, wherein said anticoagulant agent (24) is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin,

heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.

16. (Currently amended) The device of Claim 14, wherein the concentration of said fixative agent (26) positioned within said container (10) is less than about 1 ~~g/ml~~ g/ml.
17. (Currently amended) The device of Claim 14, wherein the concentration of said anticoagulant agent (24) positioned within said container (10) is less than about 0.3 g/ml.
18. (Currently amended) The device of Claim 14, wherein the compounds (22) further ~~includes~~ include a polyacrylic acid (28).
19. (Cancelled)
20. (Previously presented) The device of Claim 14, wherein said cells are selected from the group consisting of whole blood, epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.
21. (Currently amended) The device of Claim 14, wherein said compounds (22) are sterile.
22. (Cancelled)
23. (Currently amended) A kit comprising the device of Claim 14 and at least one component (32) selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

24-26. (Cancelled)

27. (Currently amended) A method for preparing mammalian cells for analysis, said method comprising the steps of:

- (a) providing a closed collection container (10) for collecting a final composition (30) having a volume of 100 parts, said container (10) having an internal pressure less than atmospheric pressure outside said container, wherein said collection container (10) contains compounds (22) including an anticoagulant agent (24) and a fixative agent (26) selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoylol-5,5 dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof inside said tube, ~~wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells~~ wherein said compounds (22) are in a volume of no greater than 2 parts; and
- (b) collecting said cells in said collection container (10).

28. (New) The method of Claim 1, wherein said compounds (22) are in a volume of no greater than 1.5 parts.

29. (New) The method Claim 28, wherein said compounds (22) are in a volume of no greater than 1 part.

30. (New) The method of Claim 3, wherein the concentration of said fixative agent (26) preloaded in said tube (12) is less than about 0.75 g/ml.

31. (New) The method of Claim 30, wherein the concentration of said fixative agent (26) preloaded in said tube (12) is less than about 0.5 g/ml.
32. (New) The method of Claim 4, wherein the concentration of said anticoagulant agent (24) preloaded in said tube (12) is less than about 0.2 g/ml.
33. (New) The method of Claim 32, wherein the concentration of said anticoagulant agent (24) preloaded in said tube (12) is less than about 0.15 g/ml.
34. (New) The device of Claim 14, wherein said compounds (22) are in a volume of no greater than 1.5 parts.
35. (New) The device of Claim 34, wherein said compounds (22) are in a volume of no greater than 1 part.
36. (New) The device of Claim 16, wherein the concentration of said fixative agent (26) positioned within said container (10) is less than about 0.75 g/ml.
37. (New) The device of Claim 36, wherein the concentration of said fixative agent (26) positioned within said container (10) is less than about 0.5 g/ml.
38. (New) The device of Claim 17, wherein the concentration of said anticoagulant agent (24) positioned within said container (10) is less than about 0.2 g/ml.
39. (New) The device of Claim 38, wherein the concentration of said anticoagulant agent (24) positioned within said container (10) is less than about 0.15 g/ml.
40. (New) A method for preparing mammalian whole blood cells for analysis, said method comprising:
 - (a) providing a collection container (10) for receiving a whole blood sample volume of 100 parts;

- (b) introducing into the collection container (10) a volume of no greater than 2 parts of compounds (22) that include an anticoagulant agent (24) and a fixative agent (26) selected from the group consisting of diazolidinyl urea, imidazolidinyl urea and a mixture thereof;
 - (c) evacuating the collection container (10) to an internal pressure that is less than atmospheric pressure outside said container;
 - (d) drawing a volume of 100 parts of a whole blood sample into the collection container (10); and
 - (e) mixing the compounds (22) with the whole blood sample in the collection container (10) so that cells of the whole blood sample are contacted with the compounds (22).
41. (New) The method of Claim 40, wherein the compounds (22) consist essentially of the anticoagulant agent (24) and the fixative agent (26) selected from diazolidinyl urea, imidazolidinyl urea, and a mixture thereof.
42. (New) The method of Claim 41, wherein the anticoagulant agent (24) is selected from ethylene diamine tetra acetic acid (EDTA), salts of EDTA, and a mixture thereof.
43. (New) The method of Claim 42, wherein the anticoagulant agent (24) is K₃EDTA present in an amount of less than about 0.3 g/ml.
44. (New) The method of Claim 41, wherein the fixative agent (26) consists of diazolidinyl urea present in an amount of less than 1 g/ml.
45. (New) The method of Claim 40, said method further comprising storing the whole blood sample in the collection container (10) after mixing and prior to analyzing.
46. (New) The method of claim 45, wherein said whole blood sample is stored at ambient temperature for a period of at least 3 days prior to analyzing.

47. (New) The method of Claim 40, said method further comprising transporting the whole blood sample in the collection container (10) from the collection site to the analysis site.
48. (New) The method of Claim 45, wherein said analyzing includes screening the whole blood cells for HIV.
49. (New) A method of screening a subject for abnormal cells or tissues, comprising the steps of:
- (a) collecting a cell or tissue sample from said subject using the device (100) of Claim 14;
 - (b) analyzing collected cell or tissue sample for abnormality using a flow cytometer, a hematology analyzer, or a combination thereof; and
 - (c) providing the results of analysis for identification.
50. (New) The method according to claim 49, wherein said abnormal cells or tissues are indicative of a disease selected from the group consisting of HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.